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APPLICATION NO. **FILING DATE** FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 09/362,598 07/28/99 WEINSTOCK .HM12/0412 **EXAMINER** KATHLEEN M WILLIAMS LEE, L BANNER & WITCOFF LTD 28 STATE STREET PAPER NUMBER **ART UNIT** 28 FL00R 1645 BOSTON MA 02109 04/12/00 DATE MAILED:

Please find below and/or attached an Office communication concerning this application r proceeding.

Commissioner of Patents and Trad marks



Office Action Summary

Application No. 09/362,598

Li Lee

Examiner

Group Art Unit

1645

Weinstock et al



X Responsive to communication(s) filed on <u>Jan 14, 2000</u>
This action is FINAL.
Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quay/1835 C.D. 11; 453 O.G. 213.
A shortened statutory period for response to this action is set to expire3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).
Disposition of Claim
☐ Claim(s) 1-32 is/are pending in the applicat
Of the above, claim(s) <u>1-23</u> is/are withdrawn from consideration
Claim(s) is/are allowed.
Claim(s) is/are objected to.
☐ Claims are subject to restriction or election requiremen
Application Papers
☑ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on is ☐ approved ☐disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.
Priority under 35 U.S.C. § 119
Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐Some* None of the CERTIFIED copies of the priority documents have been
received.
 □ received in Application No. (Series Code/Serial Number) □ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
*Certified copies not received:
Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
Attachment(s) X Notice of References Cited, PTO-892
Notice of References Cites, 1.10 control of the Properties of References Cites, 1.10 control of Ref
☐ Interview Summary, PTO-413
☑ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152
SEE OFFICE ACTION ON THE FOLLOWING PAGES

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DETAILED ACTION

Election/Restriction

1. Applicant's election without traverse of Group VII, claims 24-32 in Paper No. 7 is acknowledged.

Information Disclosure Statement

2. Items listed on form PTO-1449 filed on Sep 13, 1999 have be considered by the examiner.

Drawings

3. This application has been filed with informal drawings which are acceptable for examination purposes only. The drawings are objected to by the draftsperson under 37 C.R.F. 1.84 or 1.152. See PTO-948 for details. Correction of the noted defects can be deferred until the application is allowed by the examiner.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

5. Claims 24-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Kullberg et al (J Immunol May 15, 1992).

Claims 24-32 are drawn to a method of screening a helminthic parasite preparation for one or more components that reduce an excessive Th1 immune response.

Kullberg et al teach a method of screening a helminthic parasite preparation for components which induces a down-regulation of Th1 responses (Abstract). Kullberg et al also teach assaying the preparation in vitro and in vivo (Materials and Methods). The method of screening helminthic parasite preparation of Kullberg et al does not have exactly same steps as claimed method. However, the method of Kullberg et al screens same helminthic parasite preparation components and the screened components have same biological property as claimed method can screen-helminthic parasite preparation components which are capable of reducing an excessive Th1 immune response. Thus, Kullberg et al meet the limitation of the claims.

6. Claims 24-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Moyle et al. (US 5,708141, Jan 13, 1998).

Claims 24-31 are drawn to a method of screening a helminthic parasite preparation for one or more components that reduce an excessive Th1 immune response which is indicated by modulation of inflammation (at the specification, page 21, second paragraph).

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Moyle et al teach a method of screening a helminthic parasite preparation for components which act as anti-inflammatory compounds function as inhibitor of neutrophil activation (Abstract and columns 2, lines 61-67, column 3, lines 1-25, column 13, lines 15-33, and column 7, lines 50-65) - a indicative of reduced excessive Th1 immune response. Moyle et al also teach using chromatographic separation techniques for the screening (column 7, lines 50-65 and Examples) and assaying the preparation in vitro (Examples A and B).

Claim Rejections - 35 USC § 103

- 7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 8. Claims 24-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moyle et al. (US 5,708141, Jan 13, 1998) and Kullberg et al. (J Immunol May 15, 1992).

Moyle et al teach a method of screening a helminthic parasite preparation for components as applied in 102 rejection above. Moyle et al do not expressly assaying the preparation in vivo. However, Moyle et al clearly teach that the screened components can be used in vivo (column 15, lines 31-67) and Kullberg et al teach a method of screening a helminthic parasite preparation for components assaying the preparation in vivo.

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Therefore, it would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to assay the preparation of Moyle et al in vivo as taught by Kullberg et al. because the known benefit of the components preparation of Moyle et al will be useful in vivo in treating a variety of clinical disorders (column 13, 15-34).

Thus, the claimed invention as a whole was clearly prima facie obvious.

Status of Claims

9. No claims are allowed. All claims stand rejected.

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1645 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Lee whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995.

Li Lee April 5, 2000

